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PATENT
Attorney Docket No.: JHU1320-4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lee and Hyunh Art Unit: 1647
Application No.: 09/880,708 Examiner: D. Romeo
Filed: June 12, 2001
Title: GROWTH DIFFERENTIATION FACTOR-5

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ATTN: BOX NON-FEE AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO THE REQUEST TO ELECT A SPECIES

Sir:

Responsive to the Office Action mailed October 2, 2002 (Paper No. 8), in connection with the above-identified patent application, consideration of the following remarks is respectfully requested.

Election 1

It is stated in the Office Action that the claims are directed to the following patentably distinct species:

- 1) detectable label (claim 7);
- 2) hapten (claim 9); and
- 3) solid phase carrier (claim 13).

Election 2

It is further stated that each of the species set forth above is generic to additional species, as follows:

CERTIFICATION UNDER 37 CFR §1.8	
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, November 1, 2002 , in an envelope addressed to: ATTN: BOX NON-FEE AMENDMENT, Commissioner for Patents, Washington, D.C. 20231.	
Cecilia Tobin (Name of Person Mailing Paper)	
<i>Cecilia Tobin</i> (Signature)	November 1, 2002 (Date)

- 1) species of detectable label - a radioisotope, a fluorescent compound, a bioluminescent compound, a chemiluminescent compound, an enzyme, a colloidal metal, a phosphorescent compound, or a paramagnetic isotope (claim 8);
- 2) species of hapten - biotin, dinitrophenyl, puridoxal, or fluorescein (claim 10); and
- 3) species of solid phase carrier - glass, polystyrene, polypropylene, polyethylene, dextran, nylon, amylase, natural cellulose, modified cellulose, polyacrylamide, agarose or magnetite (claim 14).

Although Applicants traverse the requirement to elect a species for the reasons set forth below, in order to be fully responsive to the Action, Applicants elect 1) the species set forth as "detectable label", and 2) the species of detectable label set forth as "a fluorescent compound". It is noted that claims 1 to 8 are readable on the elected species.

The requirement to elect one of the species set forth in "Election 1", above, is traversed generally because the claimed methods encompass immunoassays using an antibody specific for GDF-5, which, prior to Applicants' disclosure was not known. As such, the point of novelty of the claimed invention includes anti-GDF-5 antibodies, which were not previously known. Applicants submit that a search by the Examiner of anti-GDF-5 antibodies will not reveal any art and, therefore, that there will not likely be a need to further limit the search to an anti-GDF-5 antibody linked to a second molecule, i.e., to a detectable label, a hapten, or a solid support. Similarly, the species election requirement is traversed with respect to "Election 2". Accordingly, it is submitted that it would not be an undue burden for the Examiner to rejoin all of the species and examine them together because a search of anti-GDF-5 antibodies should not reveal any references.

For the following reasons, Applicants also traverse the species election with respect to Election 1 and Election 2, as set forth above. With respect to "Election 1", the requirement to elect a species is traversed specifically with respect to the species set forth as "detectable label" and "haptens" because each provides a means for detecting an antibody to which the molecule is bound (see specification at page 16, lines 11-21). Furthermore, while claims 7 and 9 are written as separate claims, in part because the "haptens" of claim 9 can be detected using a second binding reagent such as an antibody or avidin, there is substantial overlap between the "detectable labels" as exemplified in claim 8 and the "haptens" as exemplified in claim 10. For example, the haptens of claim 9 include fluorescein (claim 10). However, fluorescein also is a fluorescent compound and, therefore, would be encompassed with the elected fluorescent compounds. As such, a search of the elected species - detectable label, and fluorescent compounds - would of necessity reveal art relevant to the hapten, fluorescein. As such, it is respectfully requested that the species set forth as "detectable labels" and "haptens" be rejoined because each species provides a means to detect an antibody to which the detectable label or hapten is bound, and because there is overlap among the exemplified species, particularly the elected species "fluorescent compounds."

With respect to "Election 2", the requirement to elect a species of "detectable label" is traversed because species of detectable labels as set forth in claim 8 (and claim 10) share a commonality of operation, function and effect (MPEP § 806.04(e)). For example, each of the detectable labels set forth as a radioisotope, a fluorescent compound, a phosphorescent compound, and a bioluminescent compound "functions" by emitting electromagnetic radiation, which provides the means for detecting the label. Furthermore, each of the detectable labels of claim 8 (as well as the haptens of claim 10) share a common "effect" of allowing detection of a molecule attached thereto (e.g., an anti-GDF-5 antibody). As such, detectable labels as set forth in claim 8 (as well as at least the hapten fluorescein in claim 10) share a commonality of operation, function or effect and, therefore, properly should be examined together. Accordingly, it is respectfully request that the

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requirement to elect a species of detectable label be removed generally, and particularly with respect to those detectable labels that function by emitting electromagnetic radiation.

In summary, it is submitted that the species of "detectable label" and "hapten" share considerable overlap, particularly with respect to the further elected species "a fluorescent compound", and, therefore, would result in duplicative searches if divided. In addition, it is submitted that the species encompassed within "a detectable label" and "hapten" share a commonality of operation, function and effect, and, therefore, should not be subject to the requirement to elect a species (MPEP § 806.04(e)). Accordingly, it is respectfully requested that the species set forth as "a detectable label" and "hapten" be rejoined and considered generic with respect to means for detecting a molecule to which either is bound, and that the further species encompassed therein be rejoined, particularly those that function as a means for detection due to emission of an electromagnetic radiation.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, the Commissioner is authorized to charge any fee (or credit any overpayment) to Deposit Acct. No. 50-1355.

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The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

Respectfully submitted,

Dated: November 1, 2002



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